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10/807,655	03/24/2004	Neal A. Rakow	57968US004	3903

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EXAMINER	
AKRAM, IMRAN	
ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/807,655	RAKOW ET AL.	
	Examiner	Art Unit	
	IMRAN AKRAM	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,43 and 45-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *43 and 55* is/are allowed.

6)☒ Claim(s) *1-4,6-10,17-20,22-30,32-35,45,46 and 48-54* is/are rejected.

7)☒ Claim(s) *5,11-16,21,31 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Examiner respectfully withdraws objection to specification for being improper. The supposed error was found in the patent application publication, not in the specification provided by the applicant.

2. Applicant's arguments with respect to claims 1-2, 6-10, 17-19, 23-29, 32, 34, 41-43, 45, and 46 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

3. Regarding claims 1-3, 7-9, 45 applicant's arguments involve the combination of the Drewes and Bogart references. Due to the amendment filed on 12/26/07, however, the rejection is no longer an obviousness type but rather one of anticipation. Claims 41 and 42 have been cancelled.

4. Regarding claim 6, applicant's arguments involve the combination of the Burrell reference with the invention of Drewes and Bogart. The rejection is now the combination of Burrell with only Drewes--in a obviousness rejection that includes all limitations *when combined* for the reasons of one of ordinary skill in the art would have as disclosed below.

5. Regarding claims 29 and 46, applicant's arguments involve the combination of the Eyster reference with the invention of Drewes and Bogart. The rejection is now the combination of Eyster with only Drewes--in a obviousness rejection that includes all limitations *when combined* for the reasons of one of ordinary skill in the art would have as disclosed below. Claim 43 is now found to be allowable.

6. Regarding claim 35, applicant's arguments involve the combination of the Stewart reference with the invention of Drewes and Bogart. The rejection is now the combination of Eyster with only Drewes--in a obviousness rejection that includes all limitations *when combined* for the reasons of one of ordinary skill in the art would have as disclosed below.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 7-10, 17-20, 22-28, 34, 45, and 48-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Drewes (US 7,153,651 B1).

9. Regarding claim 1, Drewes discloses a colorimetric sensor for measuring one or both of the presence and concentration of an analyte, said calorimetric sensor comprising: a reflective layer (the support layer of column 12, lines 45-50); a detection layer over the reflective layer (the Optically Functional layer of column 13, lines 53-62), the detection layer comprising at least one polymer component (column 15, lines 2-17), said detection layer being capable of a change in optical thickness upon exposure to said analyte (column 14, lines 39-47); and a semi-reflective layer over the detection

layer, the semi-reflective layer having an index of refraction different from the index of refraction of the detection layer (see attachment layer of column 15, lines 42-67), wherein at least a portion of the semi-reflective layer is permeable to said analyte (see claim 1) as is the reflective layer (column 12, lines 22-38). Examiner makes an argument of inherency for reflective, semi-reflective, and refractive index properties for the different embodiments of reference invention.

10. Regarding claim 2, Drewes discloses that the reflective layer comprises a metal (column 12, lines 11-21) as does the semi-reflective layer (column 15, lines 42-56).

11. Regarding claim 3, Drewes discloses the semi-reflective layer to be substantially continuous (claim 1).

12. Regarding claim 4, Drewes inherently discloses that the semi-reflective layer has a differential permeability such that the semi-reflective layer has a higher analyte permeability at a first location on an upper surface of the semi-reflective layer and a lower analyte permeability at a second location on the upper surface since the degree of differentiation is not claimed and perfect uniformity is impossible.

13. Regarding claims 7 and 8, Drewes discloses that the semi-reflective layer comprises a single layer of semi-reflective material on an outer surface of the detection layer opposite the reflective layer (see figure 1).

14. Regarding claim 9, Drewes discloses that the detection layer further comprises an inorganic material (column 13, lines 53-62), said inorganic material being within a given layer containing the at least one polymer component or in a layer separate from the at least one polymer component (column 15, lines 2-17).

15. Regarding claim 10, Drewes discloses a masking layer (see receptive layer of claim 1) over the attachment layer.

16. Regarding claims 17 and 18, Drewes discloses the detection layer to be porous (column 11, lines 3-19) and of material having microporosity (column 10, lines 60-61).

17. Regarding claims 19 and 20, Drewes discloses that the detection layer comprises two or more polymer components (column 15, lines 2-17) and wherein the optical thickness of each polymer component changes in the presence of a different analyte (column 14, lines 21-25).

18. Regarding claim 22, Drewes inherently discloses that the detection layer has a first thickness in a first location of the detection layer and a second thickness in a second location of the detection layer, said second thickness being different from said first thickness since the degree of differentiation is not claimed and perfect uniformity is impossible.

19. Regarding claim 23, Drewes discloses a permeable reflective layer (column 12, lines 48-52).

20. Regarding claim 24 and 25, Drewes discloses a sensor that is gold when free of analyte and becomes blue when exposed (column 14, lines 39-47).

21. Regarding claims 26-28, while Drewes discloses embodiments wherein biomolecules are included in the receptive layer (column 9, line 37), the reference also discloses embodiments where no biomolecules are mentioned.

22. Regarding claim 34, Drewes discloses the use of light with the sensor. Inherently, this is from a light source.

23. Regarding claim 45, Drewes discloses a colorimetric sensor for measuring one or both of the presence and concentration of an analyte, said calorimetric sensor comprising: a reflective layer (the support layer of column 12, lines 45-50); a detection layer over the reflective layer (the Optically Functional layer of column 13, lines 53-62), the detection layer comprising at least one polymer component (column 15, lines 2-17), said detection layer being capable of a change in optical thickness upon exposure to said analyte (column 14, lines 39-47); and a semi-reflective layer over the detection layer, the semi-reflective layer having an index of refraction different from the index of refraction of the detection layer (see attachment layer of column 15, lines 42-67), wherein at least a portion of the semi-reflective layer is permeable to said analyte (see claim 1) as is the reflective layer (column 12, lines 22-38). Examiner makes an argument of inherency for reflective, semi-reflective, and refractive index properties for the different embodiments of reference invention. Drewes discloses that the detection layer further comprises an inorganic material (column 13, lines 53-62), said inorganic material being within a given layer containing the at least one polymer component or in a layer separate from the at least one polymer component (column 15, lines 2-17). Drewes discloses that the detection layer comprises two or more polymer components (column 15, lines 2-17) and wherein the optical thickness of each polymer component changes in the presence of a different analyte (column 14, lines 21-25).

24. Regarding claim 48, Drewes discloses the semi-reflective layer to be substantially continuous (claim 1).

25. Regarding claim 49, Drewes discloses that the detection layer further comprises an inorganic material (column 13, lines 53-62).

26. Regarding claim 50, Drewes discloses that the detection layer comprises at least two different polymeric components, wherein the polymeric components are (1) blended with one another, (2) within a given layer but not blended with one another, (3) in a layer separate from one another, or (4) any combination of (1) to (3) (column 15, lines 2-17).

27. Regarding claim 51, Drewes discloses a permeable reflective layer (column 12, lines 48-52).

28. Regarding claim 52, Drewes discloses the semi-reflective layer to be substantially continuous (claim 1).

29. Regarding claim 53, Drewes discloses the semi-reflective layer to be substantially continuous (claim 1) and a permeable reflective layer (column 12, lines 48-52).

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

31. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

32. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

33. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drewes as applied to claim 1 above, and further in view of Burrell (US 5,124,172).

34. Drewes does not disclose a pattern of wells beneath a surface of the semi-reflective layer and extending a depth into the detection layer. Burrell, however, discloses a detection layer with wells (see figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include wells in the detection layer because Burrell discloses this feature as a known method to increase surface area for the analytes to be tested. The claim would have been obvious because

the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

35. Claims 29, 30, 46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drewes as applied to claims 1, 29, 45, and 29, respectively, above, and further in view of Eyster (US 2003/0207454).

36. Regarding claims 29, 30, and 46, Drewes does not disclose an array of sensor. However, Eyster discloses an array of sensors varying in properties (see claim 1 and paragraph 98). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an array of sensors. The claim would have been obvious because the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

37. Regarding claim 54, Drewes discloses a molecular receptor in the detection layer of the at least one colorimetric sensor (see example 6).

38. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drewes as applied to claim 1 above, and further in view of Bogart (US 5,869,272).

39. Drewes does not disclose a housing for the colorimetric sensor. Bogart does, however, disclose a housing at least partially enclosing the colorimetric sensor, wherein the housing comprises at least one opening positioned above the semi-reflective layer, said at least one opening providing a restricted view of an upper surface of the semi-reflective layer (see figure 8E). It would have been obvious to one having ordinary skill

in the art at the time the invention was made to enclose the sensor in the device of Bogart for concealing the upper surface of the top layer. The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

40. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drewes as applied to claim 34 above, and further in view of Stewart (US 4,877,747).

41. Drewes does not disclose a photodetector. Stewart, however, discloses a photodetector **D** (see figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a photodetector to capture the light that is reflected off the sensor. And while Drewes does not specifically disclose the use of a photodetector, both references disclose the need to read/detect the light reflected. A photodetector is a general class of devices for this purpose.

Allowable Subject Matter

42. Claims 43 and 55 are allowed.

43. Claims 5, 11-16, 21, 31, 33, and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

44. The following is a statement of reasons for the indication of allowable subject matter: The use of islands or patterns in the semi-reflective layer, differential permeability and thickness of the various layers on various parts of the respective layers

in a pattern formation, and arrays sharing layers of the sensors are not known in the prior art. No motivation for combination was found.

Conclusion

45. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IMRAN AKRAM whose telephone number is (571)270-3241. The examiner can normally be reached on 10-7 Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on 571-272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IA

/Alexa D. Neckel/
Supervisory Patent Examiner, Art Unit 1795